### Safe Disposal of Medications and September 25<sup>th</sup> Take-Back Events <u>Questions and Answers</u>

#### General

### Who is sponsoring the September 25<sup>th</sup> national drug take back event?

• The Drug Enforcement Administration.

#### How is the EPA involved?

• EPA supports the DEA's effort to control and dispose of unused medications for three main reasons: To protect the health of the environment, safeguard children and pets from accidental poisonings; and to prevent diversion of controlled substances such as narcotics.

#### What is the preferred method to get rid of unused or unwanted medications?

- The preferred method to get rid of medications that are unused or unwanted is to take them to a drug "take-back" program in your community.
- Incineration or other methods of destruction that comply with federal and state laws is the most common practice to get rid of unused medications in a more environmentally preferred manner.

## Should we be worried about ecological and/or human health effects due to the occurrence of pharmaceuticals in water?

• Studies have shown that pharmaceuticals are present in some of our nation's waterbodies. Further research suggests that there may be some ecological harm when certain drugs are present. To date no evidence has been found of human health effects from pharmaceuticals in the environment.

#### What are the overall scientific concerns?

- Large quantities of pharmaceuticals can enter the environment after use by individuals or domestic animals.
- Sewage systems are not equipped for removal of pharmaceuticals. Currently, there are no
  municipal sewage treatment plants that are engineered specifically for pharmaceutical
  removal or for other unregulated contaminants. Effective removal of pharmaceuticals
  from treatment plants varies based on the type of chemical and on the individual sewage
  treatment facilities.
- The overall risks posed to aquatic ecosystems, and to humans are unknown, largely because the concentrations are so low. While the major concerns have been the resistance to antibiotics and disruption of aquatic life endocrine systems (the system of glands that produce hormones that help control the body's metabolic activity) by natural and synthetic sex steroids, many other pharmaceuticals have unknown consequences. There are no known human health effects from such low-level exposures in drinking water, but special scenarios (one example being fetal exposure to low levels of medications that a mother would ordinarily be avoiding) require more investigation.
- In addition to antibiotics and steroids, over 100 individual pharmaceuticals have been identified (as of 2007) in environmental samples and drinking water.

#### Have effects to aquatic life been seen in the natural environment?

- One study, (an experimental whole lake study) conducted by Canadian scientists (with EPA collaboration), assessed the impact of an endocrine disruptor on the sustainability of a wild fish population. The seven year study involved the addition of a synthetic estrogen (17α ethinyl estradiol) that is used in birth control pills to a natural lake located in the Experimental Lakes Area of northwestern Ontario, Canada.
- The study showed that chronic exposure of a common species of minnow to low concentrations (5-6 parts per trillion) of the hormone led to feminization of male fish and altered reproductive fitness in female fish using molecular, protein, tissue, and individual whole body tests and measurements. Ultimately, these impacts led to a near extinction of this species from the lake.
- These observations show that the concentrations of an estrogen observed in freshwaters can impact the sustainability of wild fish populations. Based on these research findings, EPA is currently examining whether synthetic estrogen and chemicals like it occur in the natural environment at levels that could produce these effects.
- Some effects to aquatic life have been seen in laboratory settings. Laboratory studies
  have demonstrated effects to fish and other aquatic life from pharmaceuticals and
  estrogenic chemicals, however, it is largely unknown whether mixtures of these
  compounds at low-level, chronic exposures adversely impact fish populations in natural
  settings.

### Drug Disposal Guidelines/Stewardship

## Why did EPA approve flushing of certain medications as specified in the 2009 Federal Guidelines for the proper disposal of prescription drugs?

- Prescription drugs are regulated by the Food and Drug Administration (FDA)
- The Food and Drug Administration (FDA) requires that certain controlled substances be flushed down the toilet as instructed by the manufacturers' label that must be approved by FDA.
- All of the drugs specified as part of the Federal Guidelines for the proper disposal of
  prescription drugs have labels with instructions that require flushing as the disposal
  method for any unused portions of the drug.

## What is the rationale for FDA's policy on why some medicines should be disposed of by flushing?

- Reducing the risk of harm to people from accidental exposure to medicines is of paramount concern to the FDA.
- The FDA believes that the risk associated with accidental exposure to this small, select list of medicines far outweighs any potential risk associated with disposal by flushing.
- Disposing of these medicines in the sink or toilet completely eliminates the risk of harm to people in the home.

#### Why do the medications on the list have flushing directions for disposal?

• The medicines on this list of medicines recommended for disposal by flushing are safe and effective when used as prescribed, but they could be especially harmful to a child, pet, or anyone else if taken accidentally.

- Some of the possible harmful effects include breathing difficulties or heart problems possibly leading to death.
- For these reasons, FDA advises that flushing these medicines down the sink or toilet is currently the best way to immediately and permanently remove the risk of harm from the home.
- FDA continues to work with and encourage the manufacturers of these medicines to develop alternative, safe disposal systems.

## In light of the news stories about pharmaceuticals in water, does EPA plan to change its guidance to flush these drugs?

• EPA and FDA are discussing many topics of common interest concerning pharmaceuticals, including disposal issues.

## Have community sponsored take-back events had any impact on the concentrations of pharmaceuticals in the environment?

- It is important to keep pharmaceuticals out of the water.
- Drug take-back programs are an important way in which all of us can make a contribution to that effort.
- Typically, these programs do not collect information on the quantities or types of drugs being returned.
- However, 2 pilot grants by EPA's Aging Initiative in the Office of Children's Health Protection collected data on quantities and types of drugs, and compiled information that helped the state of Maine create a list of medications that when prescribed for the first time could have no more than a two week supply.

#### How many pills make up 1 pound?

• Approximately 1200 pills comprise 1 pound weight.

#### Has EPA sponsored any take-back events to promote good stewardship?

- EPA encourages responsible stewardship.
- The Agency has funded through the Office of Children's Health Protection and Environmental Education grants for pilot take-back programs (\$150K grant to the University of Maine Center on Aging for a pilot mail-in take-back program expected to begin in May; and \$150K grant to ARCHS in St. Louis for a pilot program to dispose of unwanted drugs through a regional grocery store chain as the collection point.)
- A number of EPA regions are promoting voluntary take-back programs for unwanted or unused pharmaceuticals. For example, in April 2008, the Great Lakes Region hosted a voluntary take-back week, where consumers brought in approximately 4.5 million pills which EPA responsibly disposed of.
- Other EPA regions have supported numerous take-back programs in their respective states.

## How many drugs are disposed of via flushing? What percentage of drugs is being flushed down the toilet compared to the amounts being excreted?

• There are no reliable estimates although there is general agreement that excretion is the largest source of pharmaceuticals in water.

- Assuming that the majority of prescriptions are completed and do not go unused, the
  pharmaceutical industry has estimated that only 2% 10% of unused drugs end up down
  the toilet or drain.
- However, a survey conducted in 1994 by the Poison Control Center reported that 35% (500 callers polled) of people surveyed said they flushed their unused medications down the toilet.
- Another survey conducted in King County, WA in 2006 (401 respondents) reported 20% of those polled flushed their old medications.

### **Treatment Technologies**

## What is EPA doing to ensure that public utilities have adequate and cost-effective treatment technologies to remove pharmaceuticals from drinking water?

- EPA and many other stakeholders in the water industry are working to develop treatment technologies that are more cost-effective and better at removing the range of contaminants that can occur in drinking water, including pharmaceuticals.
- The Agency and associations representing the water industry also provide considerable training and guidance to help water utilities make decisions about the most appropriate treatment for their source water.
- EPA also provides funding to states to ensure an affordable source of financing for water utilities to access for infrastructure improvements.

# Does typical drinking water treatment technology get rid of pharmaceuticals and endocrine disrupting chemicals from drinking water?

- The current filtration and other treatment that many drinking water systems have in place may be effective in removing more contaminants than just those for which they were originally designed.
- Removal efficiencies vary among treatment plants depending on the particular chemical and the individual treatment facility.
- Results from various research projects generally show a decline in pharmaceutical concentrations and detection frequencies at each stage/step of the water treatment process.
- More sophisticated treatment systems will provide more removal, but the performance of any given treatment will vary depending on the characteristics of the individual contaminant of concern which can vary widely for pharmaceuticals.
- In essence, there is no one size fits all when it comes to treatment technologies.
- Some technologies that may be most effective include: reverse osmosis, ozone disinfection, ultra-violet disinfection, chlorine disinfection and granular or powdered activated carbon.
- We are continuing to investigate this issue.